

(*Fasciola hepatica*) infestations in cattle.

(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

**§ 520.530 Cythioate oral liquid.**

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 000859 and 010042 in § 510.600 of this chapter.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984]

**§ 520.531 Cythioate tablets.**

(a) [Reserved]

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 010042 in § 510.600(c) of this chapter for use of 30-mg tablet.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5615, Feb. 14, 1984, as amended at 59 FR 26942, May 25, 1994]

**§ 520.540 Dexamethasone oral dosage forms.**

**§ 520.540a Dexamethasone powder.**

(a) *Specifications.* Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975; 41 FR 9149, Mar. 3, 1976; 52 FR 7832, Mar. 13, 1987]

**§ 520.540b Dexamethasone tablets and boluses.**

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (Cushingoid syndrome), except for emergency therapy.

(v) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each tablet contains 0.25 milligram of dexamethasone.<sup>1</sup>

(2) *Sponsors.* See Nos. 000061 and 050604 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Dogs: Administer orally at 0.25 to 1.25 milligrams per day for up to 7 days. Cats: 0.125 to 0.5 milligram per day for up to 7 days.<sup>1</sup>

(ii) *Indications for use.* In treatment of dogs and cats as an anti-inflammatory agent.<sup>1</sup>

(iii) *Limitations.* (a) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy; and they may precipitate

premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Do not use in animals with tuberculosis, chronic nephritis, Cushingoid syndrome, or peptic ulcers, except for emergency therapy.<sup>1</sup>

(c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 26273, June 23, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 50 FR 49372, Dec. 2, 1985; 52 FR 7832, Mar. 13, 1987; 55 FR 8461, Mar. 8, 1990]

#### § 520.540c Dexamethasone chewable tablets.

(a) *Specifications.* Each half-scored tablet contains 0.25 milligram of dexamethasone.<sup>1</sup>

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 0.25 to 1.25 milligrams per day.<sup>1</sup>

(2) *Indications for use.* Supportive therapy in nonspecific dermatosis and inflammatory conditions in dogs.<sup>1</sup>

(3) *Limitations.* (i) Administer by free-choice feeding or crumble over food. Administer 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.

(ii) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy; and they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iii) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infection. Do not use in animals with tuberculosis, chronic nephritis, Cushingoid syndrome, or peptic ulcers, except for emergency therapy.<sup>1</sup>

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.